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14. ABSTRACT: This registry initiates a program of epidemiological assessments of PS among Alaska Native people to study the natural history and clinical management of PS, and establishes a database of Alaska native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska Native people may be estimated as well. This registry not only would facilitate future research into PS etiology, but also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is ongoing in the same population.

The registry is designed in two phases. Phase 1 is a developmental period and is well underway at this time. During this phase, we established the data collection and dissemination protocols, a surveillance protocol received IRB approval but is pending approval by a privacy board, the registry database is complete and a pilot project in Anchorage will be initiated pending approvals. Phase 2 has not yet begun. It is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center.

15. SUBJECT TERMS

Alaska Native; Parkinson's disease; Registry; Etiology; Epidemiology; Ascertainment

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A. Introduction

Parkinsonism (PS) is a syndrome characterized by tremor, rigidity, slowness of movement, and problems with walking and balance. Parkinson's disease is the most common form of PS, accounting for about 1% of the U.S. population over age 50 years. Little information is available about trends in PS, particularly in Alaska Native people.

This registry initiates a program of epidemiological assessments of PS among Alaska Native people to study the natural history and clinical management of PS, and establishes a database of Alaska Native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska Native people may be estimated as well. This registry will not only facilitate future research into PS etiology, but will also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is commencing in the same population.

The registry is designed in two phases. Phase 1 is a developmental period that is currently ongoing. During this phase, data collection and dissemination protocols were established, necessary approvals for the registry are being obtained, and a pilot project in Anchorage will be initiated following approvals. Phase 2 is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center.

B. Body

The original aims of this registry project are:

1. Surveillance - Identify all cases of PS among AK Native people and develop an electronic registry database.
2. Broadly characterize the clinical features of PS among AK Native people
3. Identify factors influencing the clinical care and management of individual with PS and disease progression
4. Provide education on PS and its treatment to primary care physicians, other health care providers, patients, and caregivers

Through these aims, the registry initiates a program of epidemiological assessments of PS among Alaska Native people to study the natural history and clinical management of PS, and establishes a database of Alaska Native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska Native people may be estimated as well. This registry will not only facilitate future research into PS etiology, but will also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is ongoing in the same population.

The registry is designed in two phases. Phase 1 is a developmental period that is currently ongoing. During this phase, data collection and dissemination protocols were established, necessary approvals for the registry are being obtained, and a pilot project

in Anchorage will be initiated following approvals. Phase 2 is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center (ANMC).

While the original study goals would be preferable, in the context of an extremely slow regulatory process in Alaska involving multiple IRBs, 12 tribal boards, the U.S. Army Medical Research Human Research Protection Office and institutional privacy officers, the project as currently structured would effectively extend approval and conduct of the study over a decade or longer. We therefore submitted a request on August 5, 2010 to the contract specialist on this award to reduce the study aims in order to accomplish the most critical core study goals and the primary intent of the work. We subsequently requested a transfer of this award to the Parkinson's Institute. The approval of the reduced aims and award transfer are still being finalized. Therefore, this report will focus on the original approved Scope of Work and project aims.

SCOPE OF WORK

Phase 1, Development and Pilot Study:

To efficiently conduct the proposed work, a development phase is necessary. First, culturally sensitive methods and educational materials specific to the Alaska Native communities must be developed. Second, this work will not be possible without gaining the support of the tribal organizations. Once both of these are accomplished, the registry must be pilot-tested. The development phase will allow these aims to be achieved, helping to assure a successful registry. The specific tasks for this phase will include:

1. Establishing the scientific steering committee. **Status:** Complete
2. Developing an identification protocol. The primary source of parkinsonism cases will be the Indian Health Service (IHS) provider database, called the Resource and Patient Management System (RPMS), but the protocol will include identifying other possible sources that would identify other cases of parkinsonism among Alaska Natives. **Status:** Complete
3. Developing a secure Alaska Native parkinsonism registry database. **Status:** The database was designed and test data has been entered.
4. Ascertaining needs and interests of the Alaska Native community with regard to the parkinsonism registry project. **Status:** The initial survey of needs and interests is in progress. We continue to have ongoing discussions with medical staff and representatives of the tribal boards as the registry is presented statewide. There is great interest in the information that could result from the registry, e.g. is the

occurrence of parkinsonism greater in Alaska Native people than in other populations. We are asked this question wherever we present the registry project.

5. Developing a preliminary proposal for review by Alaska Native tribal organizations. Subsequent more detailed versions of the protocol will be submitted for review as they are developed as well. **Status:** The original scope of work called for the development of 1 protocol that covered all 4 aims of the registry project. The U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office suggested that we develop and submit 4 separate protocols, 1 for each specific aim.
 - a. SA1: Surveillance - Identify all cases of parkinsonism among Alaska Native people and develop an electronic registry database.
 - i. Protocol development and submission to the Alaska Area IRB— Submitted February 2009 to the Alaska Area IRB and approved by the Alaska Area IRB August 20, 2009 pending a privacy review by the Alaska Native Tribal Health Consortium privacy officer.
 - ii. The Alaska Native Tribal Health Consortium privacy officer gave approval Sept 23, 2010, for surveillance activities to begin pending a review by the Information Security Officer.
 - iii. The Information Security officer approved the registry December 1, 2010.
 - iv. The Alaska Area IRB informed us we needed additional documentation from the Alaska Native Tribal Health Consortium privacy officer regarding the review. We met this additional requirement on March 23, 2011, when the privacy officer provided us with an additional approval notice.
 - v. The surveillance protocol was submitted to the 2 Anchorage tribal boards, Alaska Native Tribal Health Consortium and SouthCentral Foundation in February 2011. Approval for the surveillance project was granted by the Alaska Native Tribal Health Consortium Board of Directors March 9, 2011. The SouthCentral Foundation reviewers determined that since the protocol submitted only covered surveillance activities and not research, their approval was not necessary.
 - vi. The most recent notice from Alaska Area IRB, April 21, 2011, requested an additional privacy review by the privacy officer at SouthCentral Foundation. This submission is now underway.
 - vii. If the current surveillance protocol is approved by the SouthCentral Foundation privacy officer, it will be submitted to the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office for final approval.
 - b. SA2 - Broadly characterize the clinical features of parkinsonism among Alaska Native people

- i. On August 5, 2010, we requested that this aim be deleted in order to accomplish the most critical core study goals and the primary intent of the work.
 - c. SA3 - Identify factors influencing the clinical care, disease progression and management of individuals with PS.
 - i. On August 5, 2010, we requested that this aim be deleted in order to accomplish the most critical core study goals and the primary intent of the work.
 - d. SA4 - Provide education on parkinsonism and its treatment to primary care physicians, other health care providers, patients, and caregivers
 - i. On August 5, 2010, we requested that this aim be restated as follows: Provide education on parkinsonism and its treatment to primary care physicians and other health care providers. Medical education seminars will enable investigators to share valuable information that will directly improve the quality of life of Alaska Native people with parkinsonism.
6. Establishing appropriate infrastructure and personnel in Alaska. **Status:** The hiring of registry abstractors is currently postponed until all regulatory approvals are obtained for the Anchorage service unit.
7. Developing detailed data collection and management procedures. **Status:** Complete
8. Developing detailed medical records abstraction protocols for data on clinical features, comorbid conditions, clinical management, and factors possibly affecting clinical management (e.g., home environment). **Status:** Complete
9. Working with communities to develop a multilevel educational program for health care providers, patients, and caregivers, addressing parkinsonism identification and management. **Status:** This activity is postponed pending a decision on the restatement of the education aim.
10. Refining the study protocol and preparing the operations manual. **Status:** The study protocol is complete. The operations manual was electronically embedded within the parkinsonism registry database.
11. IRB approval and Alaska Native tribal organization feedback on and approvals of final protocols.
We will submit separate protocols and receive approvals to begin work in Anchorage for each specific aim.
- a. SA1: Approval from the Alaska Area IRB, Anchorage privacy officers, 2 Anchorage tribal boards and the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office – **Status:** To date, the Alaska Area IRB approved the protocol. The 2 Anchorage based tribal boards finalized their reviews. The

Anchorage privacy review is underway. All other submission and reviews are pending.

- b. SA2 - **Status:** On August 5, 2010, we requested that this aim be deleted in order to accomplish the most critical core study goals and the primary intent of the work.
- c. SA3 - **Status:** On August 5, 2010, we requested that this aim be deleted in order to accomplish the most critical core study goals and the primary intent of the work.
- d. SA4 - **Status:** On August 5, 2010, we requested that this aim be restated as follows: Provide education on parkinsonism and its treatment to primary care physicians and other health care providers. Medical education seminars will enable investigators to share valuable information that will directly improve the quality of life of Alaska Native people with parkinsonism.

12. Pilot registry project among Alaska Natives residing in Anchorage Service Unit.

Status: This activity is pending final approval of Surveillance protocol (SA1) by all necessary regulatory and review boards representing the Anchorage basin.

13. Initial implementation of educational program. **Status:** This activity is pending approval of the restated education aim by the contracting officer.

14. Monitor quality and completeness of registered data, and define data collection challenges. **Status:** This activity is pending approval by the final regulatory agency for surveillance data collection in the Anchorage service unit.

Phase 2, Registry Implementation:

When the tasks of the development phase have been completed in Anchorage, we will expand the collection of parkinsonism registry data to Alaska Natives statewide. The specific tasks for this phase will include:

- 1. Abstracting information from medical records of prevalent and incident parkinsonism cases into the parkinsonism registry statewide. Prior to statewide abstraction, regional board approval must be sought in 10 regions. **Status:** The following activities are pending the initiation and completion of the pilot data project in Anchorage.
 - a. Regional, tribal board submissions
 - b. Regional, tribal board and U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office approvals.
 - c. Statewide abstraction will be phased in as regional tribal board approvals are received and the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office gives a memorandum of acceptance for each region.

2. Continuing implementation of educational program for health care providers, patients, and caregivers. **Status:** This activity is pending approval of the restated education aim by the contracting officer.
3. Reporting, analysis and publication. Initial results and analyses from the Anchorage service unit will be available upon initiation of data collection.

C. Key Research Accomplishments

- Requested revisions to the period of performance through Nov 2014, modifications to the project aims and statement of work, and a transfer of the project award from Alaska Native Tribal Health Consortium to the Parkinson's Institute.
- Posted test data in the electronic registry database and embedded the operations manual.
- Obtained additional approvals from the Alaska Native tribal Health Consortium privacy officer and prepared a request for review for the SouthCentral Foundation privacy officer.

D. Reportable Outcomes

While many milestones of phase 1 of this project were met, we are still in the process of obtaining approvals necessary to begin data collection. Until this has been accomplished and state wide data has been collected, we will not have reportable outcomes.

E. Conclusions

Phase 1 of this project is well underway. We have encountered challenges in determining an appropriate and efficient course for satisfying the regulatory needs for this project. Despite these significant delays, we have succeeded in developing the surveillance database. We hope to initiate database population in Anchorage in the coming months, and subsequently at regional sites on a continuing basis as individual tribal board approvals are received. Following the completion of state wide data collection (Phase 1 and 2) and analysis, it will be possible to draw relevant scientific conclusions.

F. References

None

G. Appendices - Alaska Native PS Registry IRBs and Tribal Boards

Table 1. Institutional Review Boards

Institution	Review Board	Status
Parkinson's Institute	Western Institutional Review Board (WIRB)	Submission pending
Alaska Native Medical Center	AK Area IRB	Approved pending SCF Privacy consult
Pacific Health Research Institute	VA Pacific Islands Health Care System	Submission pending
US Army Medical Research and Material Command	Office of Research Protections	Submission pending

Anchorage basin Tribal Board submissions completed:

1. Southcentral Foundation (SCF) (Anchorage)
2. Alaska Native Tribal Health Consortium (ANTHC) (Anchorage)

Regional Tribal board submissions pending:

1. Southeast Alaska Regional Health Corp
2. Metlakatla Indian Community
3. Ketchikan Indian Corp
4. Tanana Chiefs Conference
5. Arctic Slope Native Assoc
6. Maniilaq Association
7. Norton Sound Health Corp
8. Yukon-Kuskokwim Health Corp
9. Bristol Bay Area Health Corp
10. Kodiak Area Native Assoc